REMARKS

Claims 1 – 4, 10, and 11 are pending herein. Pursuant to the Examiner's observation, Applicants have amended independent Claim 1 to recite pet food compositions wherein the majority of omega-6 fatty acid is derived from flaxseed oil. Support for this amendment is found at page 5 of the specification and throughout. Moreover, Applicants have further amended Claim 1 to recite pet food compositions wherein the omega-3 fatty acids comprise at least about 80% alpha-linolenic acid derived from flaxseed oil, by weight of the omega-3 fatty acids. Support for this amendment is found in the specification at page 4. Claim 1 has further been amended to delete reference to "solid" foods, this being considered an unnecessary claim limitation. The limitation is re-introduced at amended Claim 10.

The Examiner has rejected various claims based on 35 U.S.C. § 103(a) in view of Reinhart, EP 0,678,247, published October 25, 1995 ("Reinhart"); and Reinhart in view of Brown *et al.*, U.S. Patent No. 4,229,485, issued October 21, 1980 ("Brown"). These rejections are traversed as follows:

The Rejection Under 35 U.S.C. § 103 in View of Reinhart, and Reinhart and Brown

The Examiner has rejected Claims 1 – 4 under 35 U.S.C. § 103 in view of Reinhart, and Claims 10 and 11 in view of Reinhart and Brown. The Examiner states that Reinhart teaches pet foods containing omega-6 and omega-3 fatty acids, at a ratio of from 3 : 1 to 10 : 1. The Examiner further states that the source of these fatty acids may be from a variety of sources, including fish oil and flax. The Examiner states that Reinhart teaches that the percentage of crude fat is 20% to 23%, but does not teach crude fat in the range of from about 7% to about 14%. The Examiner further states that Brown teaches that cat foods can be in canned or kibble form.

In response to Applicants' previous arguments, the Examiner states that criticality of the claimed limitations has not be provided in the specification. Applicants readily traverse this statement, since the non-obviousness of the claims in view of Reinhart has indeed been explicitly demonstrated. Reinhart states that Menhaden (fish) oil is a concentrated source of eicosapentaenoic acid; that flax oil is a concentrated source of alpha-linolenic acid; and that safflower oil is a concentrated source of linoleic acid. Reinhart states that each of these sources can be utilized to prepare compositions having omega-6 to omega-3 fatty acid ratios of 5 : 1; 10 : 1; 25 : 1; 50 : 1; or 100 : 1.

Rejected Claims 1 – 4 require pet foods comprising omega-6 and omega-3 fatty acids, wherein the ratio of these components is about 5 : 1. Moreover, as amended herein, Applicants require the majority of the omega-6 fatty acids to be derived from flaxseed oil and at least about 80% of alpha-linoleic acid derived from flaxseed oil, by weight of the omega-3 fatty acids.

In contrast, Reinhart fails to teach or suggest any difference among sunflower, fish or flaxseed oil, or any preference among fish or flaxseed oil, or any other source of omega-6 or omega-3 fatty acids, at any total fat level in any composition. Moreover, Reinhart fails to teach or suggest use of flaxseed oil specifically, to provide highly concentrated levels of omega-3 and omega-6 fatty acids. Indeed, as Applicants' now recite omega-6 fatty acids, the majority of which are derived from flaxseed oil, and omega-3 fatty acids, in which at least 80% is linoleic acid derived from flaxseed oil - - Reinhart fails to make any suggestion of such specifications.

The criticality of these claimed elements, as amended herein, as been demonstrated and disclosed in the present specification. Applicants have explicitly shown that at the low levels of fat recited in Applicants' claims (which are not suggested by Reinhart), there is a critical source of omega-3 fatty acids and omega-6 fatty acids which should be used. Indeed, Applicants' specification states that "whereas both fish oil and flaxseed oil can be included in the feline diet to reduce inflammatory response, flaxseed oil offers a better alternative in a lower lipid (14%) diet because flaxseed oil shows minimal immunosuppressive activity compared to fish oil." See Applicants' specification, page 12.

The Examiner has requested an understanding of the practical effect of the present discovery. As is commonly understood immunosuppressive activity is linked to inflammation, and omega-3-fatty acids have also been shown to suppress immune function, particularly in immunosuppressed individuals. See e.g., Wu and Meydani, "n-3 Polyunsaturated Fatty Acids and Immune Function, *Proc. Nutr. Soc.*, Vol 57(4), pp. 503 – 509 (1998); Meydani, "Effect of (n-3) Polyunsaturated Fatty Acids on Cytokine Production and Their Biologic Function," *Nutrition*, Vol. 12 (1 Suppl.), pp. S8 – 14 (Jan. 1996); Meydani and Dinarello, "Influence of Dietary Fatty Acids on Cytokine Production and its Clinical Implications," *Nutr. Clin. Pract.*, Vol. 8(2), pp. 65 – 72 (Apr. 1993) (abstract copies attached for the convenience of the Examiner). As such, that flaxseed oil has been shown by the inventors to contribute to minimized immunosuppressive activity is indeed exciting and presents practical ramifications of enhanced use of omega-3-fatty acids in the pet food compositions of the present invention.

Since unexpected results have been shown at this level of lipid (*i.e.*, a break-out amongst sources of omega-3 and omega-6 fatty acid), non-obviousness of Claims 1 – 4, as amended herein, has been demonstrated. Reinhart fails to teach or even suggest low levels of dietary fat (from about 7% to about 14%) in combinations with the criticality of omega-3 or omega-6 fatty acid source at this specific level.

Moreover, as Brown does nothing to remedy the deficiencies of Reinhart, the non-obviousness of Claims 10 and 11 has also been demonstrated. That Brown teaches canned and kibble cat foods is immaterial to the inventive discoveries relevant to low levels of lipid in combination with the specified omega-3-fatty acid, flax seed oil.

Each of Claims 1 – 4 are therefore non-obvious in view of Reinhart and the rejection should be promptly withdrawn. Similarly, Claims 10 and 11 are non-obvious in view of Reinhart and Brown and the rejection of these claims should also be withdrawn.

CONCLUSION

Applicant therefore respectfully requests that the Examiner withdraw the rejections under 35 U.S.C. § 103(a) and allow Claims 1 – 4, 10, and 11 as amended and otherwise presented herein. If the Examiner believes that personal contact would be beneficial for disposition of the present application, the Examiner is respectfully requested to contact the undersigned.

Respectfully submitted,

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Attorney Reg. No. 43,787

January 13, 2003

1: Proc Nutr Soc. 1998 Nov;57(4):503-9. Related Article

n-3 polyunsaturated fatty acids and immune function.

Wu D, Meydani SN.

Nutritional Immunology Laboratory, Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, Boston, MA 02111, USA.

n-3 PUFA have been shown to reduce the risk of cardiovascular and inflamm diseases. However, they have also been shown to suppress T-cell-mediated immune function, an undesirable effect, especially in immuno-suppressed individuals. Studies have thus far suggested that this immuno-suppression m in part attributable to increased lipid peroxidation and decreased antioxidant (especially vitamin E) levels, which can be prevented by appropriate vitamin supplementation. Further well-designed human studies are needed to determi appropriate levels of n-3 PUFA and vitamin E supplementation to optimize t beneficial anti-inflammatory effect of n-3 PUFA and minimize their suppres effect on T-cell function.

Publication Types:
- Review
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PMID: 10096109 [PubMed - indexed for MEDLINE]

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1: Nutrition. 1996 Jan;12(1 Suppl):S8-14. Related Articles, Books,

Effect of (n-3) polyunsaturated fatty acids on cytokine productic and their biologic function.

Meydani SN.

Nutritional Immunology Laboratory, Tufts University, Boston, Massachusett USA.

Cytokines are important biologic mediators with tightly regulated production Overproduction contributes to pathogenesis of acute and chronic inflammato autoimmune, atherosclerotic, and neoplastic diseases. Animal and human stu have shown that production of cytokines can be reduced by long-chain (n-3) polyunsaturated fatty acids (PUFA). This, in turn, results in reduction of the severity of certain autoimmune, inflammatory, and atherosclerotic diseases a reduces cytokine-induced anorexia. Because these cytokines are also involve control of the host defense, substantial reduction in their production could im normal immune response. In addition, increased intake of (n-3) PUFAs withc adequate antioxidant protection could result in increased free radical formati lipid peroxidation, leading to a reduction in T cell-mediated function, natural cell activity, and macrophage cytotoxicity. These risks associated with the in of (n-3) PUFAs may be minimized without compromising its beneficial effec the intake of appropriate levels of antioxidants such as vitamin E.

Publication Types:
- Review
- Review, Tutorial

PMID: 8850212 [PubMed - indexed for MEDLINE]

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1: Nutr Clin Pract. 1993 Apr;8(2):65-72.

Influence of dietary fatty acids on cytokine production and its clinical implications.

Meydani SN, Dinarello CA.

Cytokines and eicosanoids are important biologic mediators with tightly regu production. Overproduction contributes to pathogenesis of chronic and acute inflammatory, autoimmune, atherosclerotic, and neoplastic diseases. Animal human studies have shown that production of cytokines and eicosanoids can reduced by certain dietary fatty acids, specifically those containing long-chai 3) polyunsaturated fatty acids (PUFAs). This in turn results in reduction of th severity of certain autoimmune, inflammatory, and atherosclerotic diseases. Because these cytokines are also involved in control of the host defense, substantial reduction in their production could also result in the impairment c normal immune response. Increased intake of (n-3) PUFAs without adequate antioxidant protection could result in increased free radical formation and lip peroxidation. Thus, when (n-3) PUFAs are used to reduce the pathogenesis o these diseases, its possible adverse effects should be considered and prevente

Publication Types:
- Review
- Review Literature

PMID: 8326925 [PubMed - indexed for MEDLINE]